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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WILLIAMS, LEONARD M	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/646,300	FARES ET AL.	
	Examiner	Art Unit	
	Leonard M Williams	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-38* is/are rejected.

7)☒ Claim(s) *16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Claim Objections

Claim 16 is objected to because of the following informalities: Claim 16 reads, "A cosmetic or determatological..." the examiner assumes this to have meant to be read as 'A cosmetic or dermatological...'. Appropriate correction is required.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-6, 8, 10-11, 16, 22-23, 25, 27, 28, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Castro et al. (U.S. Patent No. 6113888).

Castro et al. teach, in col. 2 lines 35-55 and claim 21, a mousse composition for topical application that includes 0.001% to about 20% of 1,2-pentanediol and 0.001% to about 20% of 2-methyl-1,3-propanediol, in col. 4 line 60 to col. 5 line 15, Castro et al. teach dermatologically active agents that can be added to the said mousse compositions as including hydrocortisone, dexamethasone, panthenol, phenol, betamethasone, and triamcinolone anticipating the "...cosmetic or dermatological composition comprising at least one steroidal hormone or anti-inflammatory agent, and a solvent for said hormone or anti-inflammatory agent comprising pentylene glycol" of claim 1,

hydrocortisone and triamcinolone are adrenocortical steroids which are androgens thus anticipating the "...composition of claim 1, wherein the hormone is an androgen" of claim 2, "the composition...comprising the steroidal anti-inflammatory agent is selected from the group consisting of triamcinolone, hydrocortisone and..." of claim 3 and the "...cosmetic or determatological composition comprising hydrocortisone...and a solvent...comprising pentylene glycol" of claim 16, the '...composition of claim 1, further comprising at least one solvent other than pentylene glycol" of claim 5 and the "...composition...further comprising at least one additional solvent other than pentylene glycol" of claim 22, the "...composition of claim 5, wherein said at least one solvent comprises a glycol" of claim 6 and the "...composition...wherein said at least one solvent is a glycol" of claim 23, the "...composition of claim 1, wherein amount of pentylene glycol is about 5 to about 70% by weight of said composition" of claim 10 and the "...composition...wherein amount of pentylene glycol is about 5 to about 70% by weight..." of claim 27, the "...composition...wherein amount of pentylene glycol is about 5 to about 25% by weight..." of claim 28, and the "...composition...wherein amount of said at least one additional solvent other than pentylene glycol is about 10% to about 70% by weight..." of claim 29.

Hydrocortisone and triamcinolone are adrenocortical steroids which are androgens thus anticipating the "...composition of claim 1, wherein the hormone is an androgen" of claim 2.

Castro et al. teach, in col. 5 lines 48-55, examples of humectants that can be used in the compositions including glycols such as 2-methyl-1,3-propanediol,

1,2-pentanediol, hexylene glycol, and propylene glycol anticipating the "...composition...wherein said at least one solvent is propylene glycol" of claims 8 and 25.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of

35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4, 7, 9, 12-15, 17-21, 24, 26, 30-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castro et al. (U.S. Patent No. 6113888) as applied to claims 1-3, 5-6, 8, 10-11, 16, 22-23, 25, 27, 28, and 29 above, in view of Cooper et al. (U.S. Patent No. 4552872), Quigley et al. (U.S. Patent No. 6075056), and further in view of Vollhardt (U.S. Patent No. 6274124).

Castro et al. is as stated above. Castro et al. does not teach hydrocortisone acetate and triamcinolone acetate and their respective percentages in the compositions, nor does Castro et al. teach butylene glycol as a solvent or that butylene glycol and propylene glycol can be used together.

Cooper et al. teach, in col. 8 lines 55-63, diol compounds for use in topical pharmaceutical corticosteroid compositions including 1,2-propanediol, 1,3-propanediol, 1,2-butanediol, 1,3-butanediol, 1,4-butanediol or mixtures of these diols.

Cooper et al. teach, in col. 8 lines 10-50, corticosteroids for use in the topical pharmaceutical compositions including hydrocortisone, hydrocortisone butyrate, hydrocortisone acetate, triamcinolone, and triamcinolone acetonide. The compositions are to contain a safe and effective amount of corticosteroid from about 0.01% to about 10%, more preferably from about 0.02% to about 5%, and most preferably from about 0.05% to about 5% of corticosteroid. In examples 1-31 Cooper et al. disclose a variety of topical pharmaceutical compositions containing various corticosteroids and diols and that the

compositions show enhanced penetration of the corticosteroids when applied topically.

Quigley et al., in col. 7 lines 30-65 and Table A, teach topical formulations that may be in the form of creams, ointments, gels, lotions, foams, powders, shampoos and/or liquid solutions comprising a steroid (0.01-2.5% by weight) and propylene glycol (5-20% by weight), wherein the steroid can be triamcinolone acetate.

Vollhardt teaches, in col. 3 lines 25-45, cosmetic and/or dermatological formulations comprising 1,2-pentanediol and at least one cosmetic or dermatological active agent in a cosmetically and/or pharmaceutically acceptable carrier for topical application to the skin. Vollhardt details that 1,2-pentanediol should preferably represent 0.5% to 6% by weight of the composition, and that 1,2-pentanediol gives improved water resistance to the compositions as compared to 1,2-propanediol and 1,2-hexanediol.

Vollhardt teaches, in col. 3 lines 50-65, that the cosmetic and/or dermatological formulations can be in the form of an emulsion, thin lotion, creamy lotion, light cream, gel, and mousse formulations.

Vollhardt teaches, in col. 4 line 50 to col. 5 line 5, that the cosmetic and/or dermatologically active agents include steroidal anti-inflammatory agents such as hydrocortisone, non-steroidal anti-inflammatory agents, anti-microbial agents and fragrances.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Castro et al. with Cooper et al. in view of Vollhardt.

One of ordinary skill in the art at the time the invention was made would have been motivated to combine Castro et al. with Cooper et al. in view of Quigley et al. and Vollhardt because Castro et al. discloses topical compositions comprising 1,2-pentanediol, an additional glycol (2-methyl-1,3-propanediol), and a dermatologically active agent (which could be hydrocortisone or triamcinolone). Cooper et al. discloses topical pharmaceutical corticosteroid compositions including 1,2-propanediol, 1,3-propanediol, 1,2-butanediol, 1,3-butanediol, 1,4-butanediol or mixtures of these diols. Cooper et al. discloses that the topical pharmaceutical corticosteroids used in the compositions include hydrocortisone, hydrocortisone butyrate, hydrocortisone acetate, triamcinolone, and triamcinolone acetonide. Quigley et al. teach topical formulations of triamcinolone acetate and propylene glycol. Vollhardt teaches cosmetic and/or dermatological formulations comprising 1,2-pentanediol and at least one cosmetic or dermatological active agent in a cosmetically and/or pharmaceutically acceptable carrier for topical application to the skin. Vollhardt teaches that the cosmetic or dermatologically active agent can be a steroidal anti-inflammatory such as hydrocortisone. Vollhardt also discloses that 1,2-pentanediol confers greater water resistance to compositions. It would have been obvious to one of ordinary skill in the art at the time the invention was made that 1,2-pentanediol could be used in the topical pharmaceutical corticosteroid

compositions of Cooper et al., in view of Vollhardt, as Castro et al. demonstrated that 1,2-pentanediol could be combined with another diol (propylene glycol or butylenes glycol or both) and that Castro et al., Cooper et al. and Vollhardt's compositions all contain the same dermatologically active agents (steroidal anti-inflammatories). Quigley et al. demonstrate that triamcinolone acetate is an acceptable steroidal anti-inflammatory for glycol formulations. The increased water resistance properties of 1,2-pentanediol containing compositions would motivate one of ordinary skill in the art to combine the compositions. A reasonable chance of success would be expected as the compositions demonstrate that 1,2-pentanediol can be combined with additional diols and all the compositions detailed include steroidal anti-inflammatory agents exemplified by hydrocortisone.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LMW

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER